Suggestions for Organizing Information for a CCOP Application

GENERAL INSTRUCTIONS

In preparing a CCOP application, you must follow the instructions provided in the **RFA CA-09-022** (*Community Clinical Oncology Program*) and the *Application for a Public Health Service Grant* **(PHS-398)** (11/2007) available at: http://grants.nih.gov/grants/forms.htm and its accompanying packet of forms.

You should refer to **RFA CA-09-022** and the **PHS-398** (11/2007) **Part I, II and III** for complete instructions.

NOTE: The PHS 398 is organized into three distinct parts, each of which is available as a separate file in MS Word and PDF versions. Applicants will need to use all three parts of the instructions to prepare a complete and acceptable application.

The PHS 398 instructions include:

Part I: *Instructions for Preparing the Application*
Part II: *Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan*
Part III: *Policies, Assurances, Definitions and Other Information*.

The sample tables provided in this document "Suggestions for Organizing Information for a CCOP Application" are provided as a supplement to the PHS-398 (11/2007), NOT A REPLACEMENT. These tables are not mandatory, however may help the applicant provide all the information required by the RFA while remaining within the page limitations (**see RFA-CA-09-022, Part II**, Section IV.2., Content and Form of Application Submission). The tables may be included in the application as part of the Resources, Progress Report and Human Subject Research sections, as appropriate.

Other information included in this document is meant to provide clarifications to CCOP applicants regarding specific sections of the PHS 398 application instructions.

Requirement of DUNS Numbers on NIH Applications - Use of the Dun and Bradstreet (D&B) Data Universal Numbering System (DUNS) number is required when applying for Federal grants or cooperative agreements. See NIH Guide Notice dated August 14, 2003 and the DUNS Q&A (MS Word) document for more information.

Other Support should NOT be submitted with the application. If this information is included in the application, the application may be returned to the applicant organization WITHOUT peer review. See PHS 398 (11/2007) **Part III** (*Policies, Assurances, Definitions, and Other Information*), **Section 1.7 - Just-in-Time Policy**. Do NOT confuse "**Research Support**" with "**Other Support**." Although they sound similar, these parts of the application are very different. See **Part III (***Policies, Assurances, Definitions, and Other Information)*.

Appendix: See PHS 398 (11/2007) **Part I** (*Instructions for Preparing and Submitting an Application*), **Section 5.7 - Appendix**, for detailed instructions. Include all pertinent information mentioned in RFA-CA-09-022.

Application Due Date: The application **due date** is indicated in RFA-CA-09-022. The standard receipt dates referenced in the PHS 398 **DO NOT apply** to applications submitted in response to RFA-CA-09-022.

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Sample Tables: To assist the applicant in providing information sufficient to permit adequate review of certain areas and also maintain clarity and brevity, the following sample tables are provided as suggested formats.

Sample Table 1 - Components
Sample Table 2 - Affiliates
Sample Table 3A - Participating Physicians
Sample Table 3B - Non-Physician Investigators (e.g.: PhD=s)
Sample Table 4 - Personnel
Sample Table 5 - Number of Newly Diagnosed Cancer Patients by Site
Sample Table 6A - Accrual to NCI Approved Cancer Treatment Clinical Trials
Sample Table 6B - Accrual to All Other Cancer Treatment Clinical Trials
Sample Table 6C - Accrual to NCI Approved Cancer Prevention/Control Clinical Trials
Sample Table 7A - Cancer Treatment Accrual (Progress Report)
Sample Table 7B - Cancer Prevention/Control Accrual (Progress Report)
Sample Table 8 - Research Base Affiliation(s)
Sample Table 9 - Projected Accrual to NCI Approved Cancer Prevention/Control Clinical Trials during the Next Year

NOTE: **There is no Sample Table for Projected Accrual to NCI Approved Cancer Treatment Clinical Trials**. Applicants should provide a narrative description of their plans for accruing to NCI-approved cancer treatment trials through their affiliated Research Bases.

NOTE: These tables should be included in the application in Resources, Progress Report and/or Human Subjects Research sections, as appropriate. If tables are included in Section 1 through 7, these will count against the page limit as referenced in RFA-CA-09-022.

NOTE: With respect to the PHS 398 page limitation, each of the Tables 1 through 9 counts as **one page**, even though an applicant may include multiple pages for one or more of these Tables (e.g. 8 pages of Table 1 will count as 1 page against the page limitation referenced in the RFA-CA-09-022).

All applicants are advised to complete ALL of the Sample Tables **except** for **Sample Tables 7A and 7B.** These two tables are for **renewal** applications only, as these tables address portions of the required progress report.

PHS 398 - Part I
Instructions for Preparing and Submitting an Application

There is no specific Form Page for the **Research Plan** – Use Continuation Page.
The **Research Plan** should include sufficient information needed for evaluation of the project. Refer to the instructions as provided in RFA-CA-08-015 under **IV.2**. **Content and Form of Application Submission**, sections 1-7 (Note: These sections substitute for Part I - PHS 398, Section 5.5 Items 2-5).
For all other sections under Part I -PHS 398 **Research Plan**, Section 5.5 Items 1 and 6-17 (where applicable) follow the instructions provided in the PHS 398.

PHS 398 (Part I) - Section 5.5 – Items 8 through 11

Create a section entitled "**Protection of Human Subjects**"

- See PHS 398 **Part II** Section 3. (*Instructions for Preparing the Human Subjects Section on Protection of Human Subjects*) Scenario F: Human Subjects Research Involving a NIH-Defined Phase III Clinical Trial
- The majority, if not all, CCOP applicants should follow the instructions and provide the information outlined under Scenario F.

The following provisos will most likely apply to CCOP applicants for the following sections under Section 4.

Section 4.1.5 – Data Safety and Monitoring Plan

A CCOP applicant is not directly responsible for the formulation of data safety and monitoring plans and/or boards. However, the CCOP applicant must discuss its requirement to follow the data safety and monitoring plan(s) for each of the Research Bases with which it is affiliated. The application should describe how the CCOP implements the Research Base(s) data safety and monitoring plan(s).

Section 4.2 – Inclusion of Women and Minorities

The CCOP applicant would address the points under this heading from the perspective of overall accrual to protocols available to the CCOP, as opposed to on a protocol by protocol basis, since a CCOP accrues to multiple protocols under the auspices of this grant.

Section 4.2.1 – Additional Instructions & Requirements When NIH-Defined Phase III Clinical Trials are Proposed

A CCOP applicant must include a narrative in this section that explains that they participate in NIH-defined phase III, accessed through their Research Bases, but are not involved in the design and/or analysis of these trials, nor does the CCOP have a complete data set on any clinical trial in which it participates. Therefore, this additional requirement is not relevant or applicable to the CCOP application.

Section 4.3 – Target/Planned Enrollment Tables for Reporting Race and Ethnicity Data

A. <u>New Applications</u> –

A new applicant should complete the **Target/Planned Enrollment Form** by providing the estimated number of enrollments by gender and ethnicity/race that the CCOP anticipates enrolling during the first year of funding as a CCOP. The applicant may use one table for Treatment Trials and one table for enrollments to Cancer Prevention and Control protocols, or combine the enrollments for both in a single table. Indicate under Study Title what data is being presented in the table, i.e. Treatment and/or Cancer Prevention and Control. Provide the period covered in the space entitled "Protocol Number."

B. <u>Renewal Application and Progress Report</u> –

A CCOP applicant should complete the **Inclusion Enrollment Report** by reporting enrollments to NCI-approved protocols that have occurred over the 3 to 5 year funding period leading up to the submission of the renewal application. The applicant may use one table for Treatment Trials and one table for enrollments to Cancer Prevention and Control protocols, or combine the enrollments for both in a single table. Indicate under Study Title what data is being presented in the table, i.e. Treatment and/or Cancer Prevention and Control. Provide the period covered in space entitled "Protocol Number."

A renewal CCOP must also complete a **Target/Planned Enrollment Form**. Follow the same instructions as outlined above for New Applications.

Section 4.4 – Inclusion of Children

- For CCOP applicants that include a pediatric component, provide the information as outlined under Part II, Section 4.4 of the PHS 398 Instructions.

- If children are excluded from the research, present an acceptable justification for the exclusion. See Part II, Section 4.4 – Justification for Exclusion of Children, Item 4.b. "The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network."

PHS 398 (Part I) - Section 5.5

Item 17 – Resource Sharing Plan(s)

17(a) Data Sharing Plan:

CCOP applicants should include a brief paragraph describing how the CCOP shares its data with its affiliated Research Bases and/or through other mechanisms, if applicable. In addition, describe the process the CCOP follows to protect the rights and confidentiality of patients/participants.

NOTE: The Research Base is responsible for describing its data sharing plans because the Research Base is the entity that receives complete data set(s) for the trials they develop, manage and ultimately publish.